

REMARKS

Claims 1, 3-11 and 14-47 are pending in the application; Claims 1 and 29 are independent. Claim 1 has been amended to recite, “first securing means disposed on the inner surface of the body, for adhesively securing at least an end of the first anatomical vessel to the inner surface of the body”. Support for the amendments is found, for example, at Page 9, Paragraph 1 to Page 13, Paragraph 1 and Figures 1A-4B of the specification. No new matter has been introduced by the amendments. Reconsideration of the pending claims in light of the following remarks is respectfully requested.

The Examiner has rejected Claims 1, 4-9, 14, 15, 29-33, and 38-47 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 3,713,441 to Thomas (hereinafter “Thomas”) in view of U.S. Patent No. 6,743,243 to Roy et al., (hereafter “Roy”) and further in view of U.S. Patent No. 6,726,923 to Iyer, et al. (hereafter “Iyer”).

Applicants respectfully submit that the rejection is overcome in light of the following remarks.

Claim 1 recites a device for creating an anastomosis between first and second anatomical vessels. The device includes, *inter alia*, a substantially cylindrical body at least partially formed by a resorbable sponge material, a first securing means for securing an end of the first anatomical vessel to the body, and a second securing means for securing a portion of the second anatomical vessel to the body. The body includes an inner surface defining a through opening configured to receive at least a portion of the first anatomical vessel. The body further includes a proximal flat surface configured to appose an outer surface of the second anatomical vessel and a distal surface distanced from the outer surface of the second anatomical vessel. Specifically, the body further includes a straight side surface, connecting the proximal surface

and the distal surface, thereby providing a uniform outer diameter of the body. The through opening extends from the proximal surface to the distal surface. The first securing means is disposed on the inner surface of the body, for adhesively securing at least an end of the first anatomical vessel to the inner surface. The second securing means is adapted to secure the outer surface of the second anatomical vessel to the proximal surface of the cylindrical body, such that a hole formed in the outer surface of the second anatomical vessel is in fluid communication with the end of the first anatomical vessel.

Claim 29 is directed to a method for creating an anastomosis between first and second anatomical vessels. Claim 29 recites, *inter alia*, the step of handling a substantially cylindrical body at least partially fabricated from a resorbable sponge material. The body includes an inner surface defining a through opening configured to receive at least a portion of the first anatomical vessel. The body further includes a proximal flat surface configured to appose an outer surface of the second anatomical vessel, a distal surface distanced from the outer surface of the second anatomical vessel, and a straight side surface connecting the proximal surface and the distal surface, thereby providing a uniform outer diameter of the cylindrical body. The through opening extends from the proximal surface to the distal surface of the cylindrical body. The method further includes adhesively attaching a portion of the first anatomical vessel to the inner surface of the cylindrical body, attaching the portion of the second anatomical vessel to said proximal surface of the cylindrical body, and creating an anastomosis between the first and second anatomical vessels and through the opening in the body.

The claimed invention contemplates a device and method for creating an end-to-side anastomosis between a graft vessel and a target vessel, eliminating the need for suturing the graft vessel to the target vessel, while still maintaining the reliability and structural strength of

the anastomosis. In addition, the claimed device is easy to operate. Specifically, in operation, when both vessels are attached to the cylindrical body, the structural support provided by the cylindrical body prevents the first vessel from swinging or moving relative to the second vessel, which is preferred in a cardiac surgical procedure, such as a coronary artery bypass surgery.

Thomas is directed to a method of using an artery-vein shunt for hemodialysis.

The shunt includes a branch (21) in the form of an elastomeric tube, and a graft material (23) secured to one end of the elastomeric tube. Specifically, the graft material is secured angularly at the end of the branch for convenience in attaching to a blood vessel (*see*, Col. 2, Lines 30-32 of Thomas). The shunt further includes an infection barrier wrap (22) constituting a contiguous extension of the graft material. The infection barrier wrap is shown as surrounding the end of the branch.

During operation, the graft material (23) is sutured to the blood vessel (*see*, Col. 2, Lines 41-43 of Thomas) and the infection barrier wrap is located under the skin at the points of exit of the arterial or venous branch. Specifically, as illustrated in Figures 1-3 of Thomas, compared to the wrap, the graft material is expanded diametrically for the convenience of suturing the graft material to the blood vessel. More specifically, the graft material is in the shape of a ring, and the wrap is in the shape of a sleeve extending from the graft ring to cover the end of the branch.

Thus, Thomas teaches a device, wherein the branch is secured at its end to the graft material, which in turn is sutured to a blood vessel to establish a fluid communication between the branch and the vessel. The wrap simply serves to cover the end of the branch for infection preventing purpose. In other words, Thomas does not disclose that the wrap is secured to the branch in order to establish a fluid communication between the branch and the vessel. The

graft material is the only functional structure for establishing the fluid communication by being secured to the branch and also sutured to the blood vessel.

The Examiner has alleged that Thomas discloses a device “comprising a substantially cylindrical body (22,23), the body formed from an opening construction material (col. 2, ll 22), the body comprising an inner surface defining a through opening configured to receive the first vessel 21...” (*see*, Page 3, Item 6, Lines 5-8 of the Office Action).

Applicants respectfully disagree with the above allegation. As discussed above, the infection barrier wrap (22) should not be interpreted as a part of the device for creating an end to side anastomosis, because the wrap is not a functional element for establishing a fluid communication between the branch and the vessel. Thus, the Examiner’s interpretation of the graft material (23) and the infection barrier wrap (22), collectively, as a cylindrical body for creating an anastomosis is improper. Applicants respectfully submit that Thomas only discloses a ring-shaped graft material secured to one end of the branch for establishing a fluid communication between the branch and the vessel, and Thomas does not disclose a cylindrical body for creating an end to side anastomosis.

Furthermore, even assuming, *arguendo*, the wrap can be interpreted as a part of the graft material, the wrap does not provide an inner surface for disposing a securing means for adhesively securing the end of the branch to the wrap.

In addition, Thomas only briefly discloses, “the branch has graft material 23 secured at one end”. Thomas does not disclose, inherently or explicitly, that the branch is received in the opening defined by the graft material.

Claims 1 and 29 also recite that the cylindrical body comprise a flat proximal surface configured to appose an outer surface of the second anatomical vessel. In this regard, the

Examiner has argued that Thomas discloses a flat proximal surface, because the proximal surface of Thomas is attached to the outer surface of the second vessel (*see*, the last three lines of Page 3 of the Office Action).

Applicants respectfully disagree. As clearly shown in Figs 1-3 of Thomas, the expanded graft material (23) is in the shape of a ring, which does not include a flat bottom surface apposing the vessel. Furthermore, the attachment of the graft material to the second vessel does not necessarily disclose a graft material having a flat surface.

Roy is relied on for the alleged teaching of an adhesive for attaching a tubular member to a vessel. Roy does not disclose a cylindrical body of an anastomosis-creating device having a flat proximal surface and a uniform diameter. Iyer is relied on for the alleged teaching of a resorbable sponge. However, neither Roy nor Iyer remedy the underlying deficiencies of Thomas with respect to Claims 1 and 29, i.e., neither Roy nor Iyer teach or fairly suggest the cylindrical body as recited in Claims 1 and 29.

Thus, none of Thomas, Roy and Iyer, taken alone or in combination, teach or fairly suggest the combination of features recited in Claims 1 and 29, from which the other claims depend.

Accordingly, the rejection of Claims 1, 4-9, 14, 15, 29-33, and 38-47 under 35 U.S.C. §103(a) based on the hypothetical combination of Thomas, Roy and Iyer is overcome, and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted
that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "F. S. DiGiglio", written in a cursive style.

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